510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance to requirements of SMDA 1990 and 21 CFR §807.92.

Submitter´s Details

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Date of Summary:	September 28, 2018

Name of Device

Trade Name:	IH-Reader 24
Device Name:	Automated blood grouping and antibody test systems.
510(k) number:	-
Device Class:	II
Product Code:	KSZ
Regulation number:	21 CFR 864.9175

Identification of the Legally Marketed Device (Predicated Device)

Trade Name:	IH-Centrifuge L
Device Name:	Manual Blood Grouping and Antibody Test Systems
510(k) number:	BK170065
Device Class:	II
Product Code:	PBC
Regulation number:	21 CFR 864.9175
Clearance Letter:	December 18, 2017

DESCRIPTION OF THE DEVICE

The IH-Reader 24 is a combination of a centrifuge and a reader designed for processing manually pipetted IH-Cards. In combination with the Data Management Software IH-Com, it is able to identify pipetting data such as patient identity or performed tests. An internal high-resolution color camera guarantees a clear image and, depending on user's authorization level, allows visualization, validation and editing of results. All these changes are traced accordingly in the database. The results can be visualized, printed and sent to a host computer, thus enabling archive, grouping and detailed search in a database.

INTENDED USE

The IH-Reader 24 is an instrument intended for the in vitro serological analysis of human blood specimens for blood grouping and antibody detection. IH-Reader 24 performs centrifugation and provides reaction grading / interpretation based on results from IH-System gel card images. In the USA, IH-Reader 24 is "Rx only".

The IH-Reader 24 may only be operated by trained personnel and is not intended for use in a direct patient environment. Use of the IH-Reader 24 is only permitted in conjunction with the corresponding software or in a configuration authorized by Bio-Rad. IH-Reader 24 is allowed to use gel cards from the IH-System authorized by Bio-Rad. The use of any material not specified in the User Manual (e.g. non-authorized substances) is under the users' responsibility.

DEVICE COMPARISON

The following table identifies IH-Centrifuge L (Bio-Rad Medical Diagnostics GmbH), FDA-cleared under BK170065, as predicate device.

Parameter	**Predicate Device** **Bio-Rad** **IH-Centrifuge L**	**Subject Device** **Bio-Rad** **IH-Reader 24**
Indications for Use	The IH-Centrifuge L is intended for centrifugation of IH-System gel cards and/or test tubes for in vitro immunohematology testing of human blood. In the USA, IH-Centrifuge L is "Rx only". The IH-Centrifuge L may only be operated by trained	The IH-Reader 24 is an instrument intended for the in vitro serological analysis of human blood specimens for blood grouping and antibody detection. IH-Reader 24 performs centrifugation and provides reaction grading / interpretation based on results

	personnel and is not intended for use in a direct patient environment. Use of the IH-Centrifuge L is only permitted in conjunction with the corresponding software or in a configuration authorized by Bio-Rad. The use of any material not specified in the User Manual (e.g. non-authorized substances) is under users' responsibility.	from IH-System gel card images. In the USA, IH-Reader 24 is "Rx only". The IH-Reader 24 may only be operated by trained personnel and is not intended for use in a direct patient environment. Use of the IH-Reader 24 is only permitted in conjunction with the corresponding software or in a configuration authorized by Bio-Rad. IH-Reader 24 is allowed to use gel cards from the IH-System authorized by Bio-Rad. The use of any material not specified in the User Manual (e.g. non-authorized substances) is under the users' responsibility.
Device	Manual Blood Grouping And Antibody Test Systems	Manual Blood Grouping And Antibody Test Systems
Regulation Classification	Class II, 21 CFR 864.9175	Class II, 21 CFR 864.9175
Product Code	PBC	PBC
Dimensions	H: 230 mm W: 380 mm D: 500 mm	H: 380 mm W: 540 mm D: 545 mm
Power Requirements (Frequency)	100-240V~ (50/60 Hz)	100-230V~ (50/60 Hz)
Operating Temperature	18°C to 25°C	18°C to 25°C
Capacity	24 IH-Cards	24 IH-Cards
Spin Heads	1 x Head 24 Cards 1 x Head 2 Racks [1,2] 1 x Head 28 Tubes (Ø10 to Ø12 mm)[1] [1] not required for the test process with IH-Cards. [2]only for pre-centrifugation	1 x Head 24 Cards

Centrifugation Specification (Head 24 Cards)	Head 24 Cards 910 rpm ± 0.5% (85 ± 0.5% rcf) Centrifugation Time in stabilized speed: 600 ± 2 (s) Acceleration/Deceleration: 17s +/-2s	Head 24 Cards 910 rpm ± 0.5% (85 ± 0.5% rcf) Centrifugation Time in stabilized speed: 600 ± 2 (s) Acceleration/Deceleration: 17s +/-2s
Control Panels	An operating panel on the front of the IH-Centrifuge L consists of a 4.3 inches color touch screen display. The display indicates the current operating status of the centrifuge.	All controls, with the exception of the power switch, are grouped on the front operating panel. 3 LED provides information about the current status of the centrifuge. Operation of the IH-Reader 24 is controlled by an external PC.
Results Reading and Reaction grading	Visually by eye.	IH-Cards are read out automatically, pictures are captured and analyzed by IH-Com software. IH-Card pictures and results are displayed on a PC screen.

PERFORMANCE TESTING

Clinical studies were performed at five US sites and one internal site which included using Bio-Rad Medical Diagnostics licensed IH-reagents and FDA licensed comparator methods. Testing of the IH-reagents included the use of the IH-Reader 24 with IH-Com. Comparative methods included different FDA cleared instruments and FDA licensed reagents for immunhematology testing. Samples were collected from both blood donors and patients at these six sites. This study included more than 16,420 tests from a diverse population in broad geographical areas.

The results of this clinical trial support the conclusion that the testing of IH-Cards for Blood Grouping and Anti-Human Globulin Testing and the corresponding Reagent Red Blood Cells tested on the IH-Reader 24 with IH-Com is safe and effective.

The yielded results demonstrate that end users, with proper training, could use the IH-Reader 24 with IH-Com to perform ABO+D cellular and serum grouping, Rh+K phenotyping, weak D testing, detection and identification of unexpected antibodies, DAT and AHG crossmatching and that the testing with the specified IH-Reagents on the IH-Reader 24 with IH-Com does generate results comparable to established FDA licensed reference reagents and FDA cleared predicate.